

CLAIMS

What is claimed is:

1. A crystalline form of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride characterized by at least one of: x-ray powder pattern substantially as shown in Fig. 1; a loss of mass of about 1 percent over a range of temperature of about forty degrees Celsius to about one-hundred eighty degrees Celsius; Raman spectrum substantially as shown in Fig. 5; and elemental analysis substantially as in Table 1.
2. The crystalline form of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride of claim 1 wherein a plurality of crystals are amassed as agglomerates.
3. The crystalline form of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride agglomerates of claim 2 wherein said plurality of crystals are amassed as generally orderly packed agglomerates.
4. A pharmaceutical composition comprising the crystalline S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride of claim 1 together with a pharmaceutically acceptable carrier.
5. A method of treating a condition wherein pathologically high production forms a part in a subject in need of such treatment comprising administering to the subject an effective amount of the crystalline S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride of claim 1.
6. A method of making the generally orderly packed agglomerate crystalline S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride of claim 3 utilizing a crystallization procedure comprising adding an anti-solvent to a solvent solution in which is dissolved S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride, thereby forming a system comprising two phases, and precipitating generally orderly packed agglomerate crystalline S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride.

7. The method of claim 6 wherein the anti-solvent solution is added to the solvent solution in which is dissolved S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride, followed by addition of seed crystals to the system.
8. The method of claim 6 wherein the anti-solvent comprises acetone.
9. The method of claim 6 wherein the solvent solution comprises 1-butanol and S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride.
10. The method of claim 6 wherein the anti-solvent comprises acetonitrile, and the solvent solution comprises *N,N*-dimethylformamide and S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride.
11. The method of claim 6 wherein the anti-solvent comprises acetone, and the solvent solution comprises 1-butanol and S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride.
12. The method of claim 7 wherein no less than about one percent by weight of the total S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride in the system is introduced as added seed crystals.
13. The method of claim 6 wherein a sufficient amount of anti-solvent is added to a solvent solution comprising S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride in a reaction vessel to form a reaction system, until one of a) turbidity or b) an oily coating on a surface of said reaction vessel is visually apparent, and adding seed crystals to said system.
14. The method of claim 7 wherein the seed crystals are created *in-situ* by at least one of: reducing the water content of the solvent solution; reducing the amount of maleic acid; or altering the rate of super-saturation generation.
15. The method of claim 6 wherein no seed crystals are added to the system, and the ratio of anti-solvent added to the system exceeds the ratio of solvent solution in which is dissolved

S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride by about one hundred and ten percent by weight that of the ratio of anti-solvent to solvent used in a system wherein seed crystals are added, to precipitate generally orderly packed agglomerate crystalline S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate hydrochloride.